IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DENISE McGRAIN *Plaintiff*	:	**CIVIL ACTION**
	:	**NO. 21-1539**
v.	:	
C.R. BARD, INC., *et al.* *Defendants*	:	

NITZA I. QUIÑONES ALEJANDRO, J. JULY 30, 2021

MEMORANDUM OPINION

INTRODUCTION

Denise McGrain ("Plaintiff") filed this personal injury action against C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Defendants"), asserting the following causes of action; *to wit*: negligence (Count I), strict liability (Counts II-IV), breach of express warranty (Count V), breach of implied warranty of merchantability (Count VI), fraudulent misrepresentation (Count VII), fraudulent concealment (Count VIII), negligent misrepresentation (Count IX), and unjust enrichment (Count X). In the complaint, Plaintiff avers that in 2003 she had a Bard G2 IVC filter ("IVC filter") device surgically implanted to treat certain medical conditions, and that in 2020 a CT abdomen scan showed two struts of the IVC filter perforating the wall of her inferior vena cava. Plaintiff further avers that the IVC filter was designed, manufactured, marketed, and distributed by Defendants.[1]

Before this Court is Defendants' motion to dismiss for failure to state a claim filed pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(6), [ECF 3], in which Defendants argue that all of Plaintiff's claims should be dismissed because, *inter alia*, either they are not recognized under

[1] This civil action was originally filed in the Court of Common Pleas of Philadelphia County, and removed by Defendants to this Court. [ECF 1]

Pennsylvania law or Plaintiff has failed to allege sufficient facts to render the claims plausible. Plaintiff opposes Defendants' motion. [ECF 8]. The issues raised by the parties have been fully briefed and are ripe for disposition. For the reasons set forth herein, Defendants' motion to dismiss is granted in its entirety. Nevertheless, Plaintiff is granted leave to amend her complaint, but *only* with respect to those claims premised on negligence (Count I), breach of express warranty (Count V), fraudulent misrepresentation (Count VII), and negligent misrepresentation (Count IX).

BACKGROUND

When ruling on a motion to dismiss, this Court must accept as true the well-pleaded, relevant allegations in the operative complaint. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). Briefly, the salient facts relevant to Defendants' motion to dismiss are:

> Plaintiff suffered from pulmonary embolus and deep vein thrombosis. [ECF 1 ¶¶ 30-31]. In 2003, Plaintiff underwent surgery at University of Pennsylvania Hospital and had a Bard G2 IVC filter implanted for the purpose of treating these conditions. [ECF 1 ¶¶ 30-31]. The Bard G2 IVC filter was designed, manufactured, marketed, and distributed by Defendants. [ECF 1 ¶¶ 8-11, 36-37].
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> On February 17, 2020, Plaintiff underwent a CT abdomen scan which "showed results of an intact retrievable infrarenal IVC filter . . . with two struts perforating through the wall of the inferior vena cava by up to 5 mm." [ECF 1 ¶¶ 33-34]. Plaintiff avers that she "experiences pain and discomfort in her abdominal area." [ECF 1 ¶ 35].

LEGAL STANDARD

As noted, when considering a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), the court "must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions." *Fowler*, 578 F.3d at 210. The court must determine "whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id*. at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). The complaint must do more than merely allege the plaintiff's entitlement to relief; it must "show such an entitlement with its

facts." *Id.* (citations omitted). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged-–but it has not 'show[n]'-–'that the pleader is entitled to relief.'" *Iqbal*, 556 U.S. at 679 (quoting Fed. R. Civ. P. 8(a)) (alterations in original). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. at 678 (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements do not suffice." *Id*. To survive a motion to dismiss under Rule 12(b)(6), "a plaintiff must allege facts sufficient to 'nudge [his] claims across the line from conceivable to plausible.'" *Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Twombly*, 550 U.S. at 570).

DISCUSSION

Defendants argue that all of Plaintiff's claims should be dismissed because, *inter alia*, either they are not recognized under Pennsylvania law or Plaintiff has failed to allege sufficient facts to satisfy the plausibility requirement. Each argument is discussed in turn.

Products Liability – Strict Liability

At Counts II-IV of the complaint, Plaintiff asserts strict liability claims premised on the IVC filter's alleged design, manufacturing, and warning defects. Defendants move to dismiss these strict liability claims on the basis that, under Pennsylvania law,[2] such claims are not legally cognizable against a medical device manufacturer. In her response, Plaintiff appears to concede

[2] The parties agree that this matter is governed by Pennsylvania law. Pennsylvania courts follow the strict liability formulation set out in § 402A of the Restatement (Second) of Torts. *See Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 394-99 (Pa. 2014). Under Pennsylvania law, there are three types of defects that give rise to a strict liability claim: (1) design defect; (2) manufacturing defect; and (3) warning defect (*i.e.*, failure to warn or inadequate warnings). *See Phillips v. A-Best Prods. Co.*, 665 A.2d 1167, 1170 (Pa. 1995); *Doughtery v. C.R. Bard*, 2012 WL 2940727, at *2 (E.D. Pa. July 18, 2012).

that her strict liability design and warning defect claims are, in fact, precluded, acknowledging that "federal courts have found that . . . Pennsylvania law prohibits strict liability claims based on a 'design' defect or a 'failure to warn.'" [ECF 8 at 11]. Indeed, this Court has previously held that such claims are barred under Pennsylvania law. *Lopez v. Ethicon*, 2020 WL 5569770, at *5 (E.D. Pa. Sept. 17, 2020) (Quiñones, J.) (predicting that the Pennsylvania Supreme Court would bar strict liability claims for design defect and failure to warn against manufacturers of prescription medical devices). Plaintiff provides this Court with no reason why it should depart from its previous holding.[3] Accordingly, this Court holds, as it did in *Lopez*, that Pennsylvania law precludes strict liability claims for design and/or warning defects against medical device manufacturers.

Plaintiff argues, however, that her strict liability *manufacturing defect* claim is viable. As this Court observed in *Lopez*, a split exists among federal district courts applying Pennsylvania law as to whether such a claim is cognizable against a medical device manufacturer.[4] *Lopez,* 2020

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[3] Plaintiff does not identify any case law allowing strict liability design defect or failure to warn claims to proceed in the medical device context. In fact, every relevant opinion Plaintiff cites holds that strict liability claims for design defect or failure to warn are not viable causes of action against manufacturers of prescription drugs or medical devices. *See Doughtery v. C.R. Bard*, 2012 WL 2940727, at *6 (E.D. Pa. July 18, 2012); *Killen v. Stryker Spine*, 2012 WL 4498865, at *3 (W.D. Pa. Sept. 28, 2012); *Tatum v. Takeda Pharms. N. Am., Inc.*, 2012 WL 5182895, at *2 (E.D. Pa. Oct. 19, 2012); *Bergstresser v. Bristol-Myers Squibb Co.*, 2013 WL 1760525, at *3 (M.D. Pa. April 24, 2013); *Kline v. Zimmer Holdings, Inc.*, 2013 WL 3279797, at *5 (W.D. Pa. Sept. 27, 2013); *Wagner v. Kimberly-Clark Corp.*, 225 F. Supp. 3d 311, 316 (E.D. Pa. 2016). This Court is aware that there exists a split on this issue in the Pennsylvania federal courts. *See, e.g., Schrecengost v. Coloplast Corp.*, 2019 WL 6465398, at *12 (W.D. Pa. Dec. 2, 2019). Notwithstanding, this Court continues to predict, as it did in *Lopez*, that the Pennsylvania Supreme Court would bar strict liability design defect or failure to warn claims against medical device manufacturers.

[4] Recognizing this split, a panel of the United States Court of Appeals for the Third Circuit ("Third Circuit") recently certified the following questions to the Pennsylvania Supreme Court:

> Under Pennsylvania law, are prescription implantable medical devices categorically subject to strict liability, categorically immune from strict liability, or immune from strict

WL 5569770 at *5 n.3. While this Court did not address this particular split in *Lopez*, it does so here and holds that Plaintiff's strict liability manufacturing defect claim is also barred for the reasons that follow.

As recently recognized by the Third Circuit in *Ebert*, the Pennsylvania Supreme Court has not directly addressed the issue of whether strict liability applies to manufacturing defect claims against medical device manufacturers. *Ebert*, 2021 WL 2655690. The Pennsylvania Supreme Court has held broadly, however, that "Comment k [to § 402A of the Restatement (Second) of Torts] . . . denies application of strict liability to products such as prescription drugs."[5] *Hahn*

> liability on a case-by-case basis? If they are immune on a case-by-case basis, what test should a court apply to determine whether a particular device is immune?

Ebert v. Bard, Inc., 2021 WL 2655690, at *5-6 (3d Cir. June 24, 2021). In the absence of dispositive guidance from the Pennsylvania Supreme Court, this Court predicts that the Pennsylvania Supreme Court would not recognize a strict liability manufacturing defect claim against Bard for its IVC filter in the instant case.

[5] Specifically, Comment k provides:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A cmt. k (emphasis in original).

v. Richter, 673 A.2d 888, 889 (Pa. 1996). The Pennsylvania Supreme Court reiterated its broad statement in *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014), holding that "for policy reasons, this Court has declined to extend strict liability into the prescription drug arena." *Id*. at 438. Although in *Hahn* and *Lance* the Pennsylvania Supreme Court addressed the issue only in the prescription drug context, the Pennsylvania Superior Court has applied the same reasoning to bar strict liability claims against manufacturers of medical devices. *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006) (finding "no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices"). Consistent with these holdings, many federal courts, including this one, have predicted that the Pennsylvania Supreme Court would extend Comment k to medical devices. *Lopez*, 2020 WL 5569770 at *5; *see also Ebert*, 2021 WL 2655690, at *4 (collecting cases).

Plaintiff argues, however, that Comment k's exemption from strict liability does not extend to manufacturing defects. In support of this argument, Plaintiff cites the Pennsylvania Supreme Court's decision in *Tincher*, 104 A.3d 328, for the proposition that "[n]o product is expressly exempt [from strict liability] and, as a result, the presumption is that strict liability may be available with respect to any product, provided that the evidence is sufficient to prove a defect." *Id*. at 386. Plaintiff's reliance on *Tincher* is misplaced. In *Tincher*, the Pennsylvania Supreme Court did not address strict liability claims in the context of either prescription drugs or medical devices; rather, it addressed the viability of homeowners' strict liability claims against the manufacturer of a fireplace component. *Id*. at 335-36. As such it is inapposite. Moreover, while the *Tincher* Court expressly overruled another Pennsylvania Supreme Court opinion, it did not overrule *Hahn* or *Lance*. *Id.* at 328 (expressly overruling *Azzarello v. Black Brothers Co.*, 391 A.2d 1020 (Pa. 1978)); *see also Lopez*, 2020 WL 5569770 at *5. In fact, the *Tincher* Court specifically noted an

exception to the general proposition that "no product is expressly exempt" by immediately following this broad statement with a "but see" citation to *Hahn*. 104 A.3d at 328 (noting that a "manufacturer [is] immune from strict liability defective design claim premised upon sale of prescription drugs without adequate warning")*; see also Kohn v. Ethicon*, 2020 WL 733126, at *4 (E.D. Pa. Feb. 13, 2020) (rejecting *Tincher*'s relevance to case involving implanted medical device). As such, the *Tincher* decision does not reflect any regression or retreat from, or limitation to, the Pennsylvania Supreme Court's holding in *Hahn*. *Lopez*, 2020 WL 5569770 at *5*; see also Rosenberg v. C.R. Bard*, 387 F. Supp. 3d 572, 580-81 (E.D. Pa. 2019) (reasoning that *Tincher* expressly recognized *Hahn*'s exception to the general rule that all products are subject to strict liability). Because the Pennsylvania Supreme Court's holdings in *Hahn* and *Lance* remain good law, Plaintiff's reliance on *Tincher* is misplaced.

This Court recognizes that the strict liability claims at issue in *Hahn* were limited to failure to warn claims. Notably, Plaintiff offers no argument as to why the Pennsylvania Supreme Court would not apply the same reasoning it employed in *Hahn* to similarly bar strict liability manufacturing defect claims. The operative language in Comment k on which the Pennsylvania Supreme Court relied to bar strict liability warning defect claims against prescription drug manufacturers provides: "Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous." Restatement (Second) of Torts § 402A cmt. k (emphasis in original). The *Hahn* Court relied on the "accompanied by proper directions and warning" language to hold that "where the adequacy of warnings associated with prescription drugs is at issue, . . . the manufacturer's negligence[] is the only recognized basis of liability." 673 A.2d at 891. Though the Pennsylvania Supreme Court has yet to address the "properly prepared" language in this same sentence of Comment k, Plaintiff has offered no basis,

and this Court is unaware of any, on which the Pennsylvania Supreme Court could interpret and apply "properly prepared" any differently than it interpreted and applied "accompanied by proper directions and warning." Accordingly, this Court predicts that the Pennsylvania Supreme Court would extend its reasoning in *Hahn* to preclude strict liability manufacturing defect claims against medical device manufacturers.

Plaintiff also fails to address the Pennsylvania Supreme Court's more recent statement in *Lance*. As noted above, as in *Hahn*, the Pennsylvania Supreme Court spoke broadly in *Lance*, stating that, "for policy reasons, [it] has declined to extend strict liability into the prescription drug arena." *Lance,* 85 A.3d at 438. Defendants argue broadly that, after *Lance*, "Pennsylvania law bars ***all*** strict liability claims in personal injury actions against medical device companies." This Court finds Defendants' post-*Lance* arguments persuasive on this point, as have numerous other district courts in this circuit. *See, e.g., Rosenberg*, 387 F. Supp. 3d at 580 (Robreno, J.) (dismissing strict liability manufacturing defect claim against medical device manufacturer and noting that Pennsylvania Superior Court holding allowing such a claim is "entitled to no weight" after *Lance*); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 833 (E.D. Pa. 2016) (Padova, J.) (dismissing strict liability manufacturing defect claim because the *Lance* Court *"*stated, <u>without qualification</u>, that 'for policy reasons this Court has declined to extend strict liability in the prescription drug arena'" (emphasis in original)); *Runner v. C. R. Bard*, 108 F. Supp. 3d 261, 266 (E.D. Pa. 2015) (Dalzell, J.) (concluding that Comment k requires dismissal of strict liability manufacturing defect claim against Bard in case involving implantable medical device); *Wilson v. Synthes USA Prods., LLC*, 116 F. Supp. 3d 463, 467 (E.D. Pa. 2015) (Schmehl, J.) (dismissing strict liability manufacturing defect claim against medical device manufacturer because Comment k "serves to impose a ban on all strict liability against medical device manufacturers"); *Terrell v. Davol, Inc.*,

2014 WL 3746532, at *5 (E.D. Pa. July 30, 2014) (Slomsky, J.) (dismissing strict liability manufacturing defect claim because neither the *Lance* nor *Hahn* Court made an exception for manufacturing defect claims in explaining the broad "principle that a strict liability claim based on a defective prescription drug is barred").[6] Notably, courts in this district have predicted that the Pennsylvania Supreme Court would bar strict liability claims against Bard in cases involving the same IVC filter at issue here. *See Keen v. C.R. Bard*, 480 F. Supp. 3d 624, 637 (E.D. Pa. 2020) (Pratter, J.) (predicting that the Court would apply Comment k to bar all three strict liability claims); *Ebert v. C.R. Bard, Inc.*, 459 F. Supp. 3d 637, 653 (E.D. Pa. 2020) (Pappert, J.) (predicting that because "the Bard G2 filter is an 'unavoidably unsafe product' . . . the Pennsylvania Supreme Court would apply [C]omment k to the filter, thereby shielding Bard from a strict liability claim"). Courts in this district have also continued to predict the same in cases involving other medical devices. *See, e.g., Kohn*, 2020 WL 733126, at *5 (Tucker, J.) (finding that strict liability claims cannot proceed against medical device manufacturers under Pennsylvania law).

In the absence of further guidance from the Pennsylvania Supreme Court and given the apparent breadth of its statement in both *Hahn* and *Lance*, this Court predicts, as have other courts, that the Pennsylvania Supreme Court would preclude strict liability manufacturing defect claims against medical device manufacturers. Consequently, Plaintiff's strict liability claims for manufacturing defect, design defect, and failure to warn are barred, as a matter of law, and Counts II-IV are dismissed with prejudice.

Breach of Implied Warranty of Merchantability

At Count VI, Plaintiff asserts a claim for breach of the implied warranty of merchantability. Defendants move to dismiss this claim on the grounds that it is barred for the same reasons as

[6] Notably, of the six district court opinions Plaintiff cites in support of her strict liability manufacturing defect claim, only one was published after *Lance*.

Plaintiff's strict liability claims. Though Plaintiff argues that her implied warranty claim is legally viable, she does not provide any reasoning or case law that supports this argument. Regardless, this Court agrees with Defendants.

An implied warranty of merchantability arises whenever goods are sold by a person who is a merchant with respect to goods of that kind. *See* 13 Pa. Cons. Stat. § 2314. The essence of the warranty of merchantability is that the item sold is fit for the ordinary purposes for which such goods are used. *Wisniewski v. Great Atlantic and Pacific Tea Company*, 323 A.2d 744, 746–747 (Pa. 1974); 13 Pa. Cons. Stat. § 2314(b)(3). The Pennsylvania Supreme Court has indicated that, while implied warranty of merchantability claims are not identical to strict liability claims, they are "co-extensive." *Williams v. West Penn Power Co.*, 467 A.2d 811, 815 n.16 (Pa. 1983). When applying Pennsylvania law, the Third Circuit has endorsed the general understanding that the elements of the two theories of liability are "essentially the same." *Gumbs v. Int'l Harvester, Inc.*, 718 F.2d 88, 94 (3d Cir. 1983) (citations omitted) (interpreting the identical provision of the Uniform Commercial Code); *see also Reese v. Ford Motor Co.*, 499 F. App'x 163, 166 (3d Cir. 2012) (citing *Gumbs* and reaching the same conclusion with respect to 13 Pa. Cons. Stat. § 2314).

In *Makripodis ex rel. Makripodis v. Merrell-Dow Pharms., Inc.*, 523 A.2d 374, 594 (Pa. Super. Ct. 1987), the Pennsylvania Superior Court applied this principle in the prescription drug arena. The *Makripodis* Court held that "the very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for 'ordinary purposes,'" affirming the lower court's dismissal of the claim. *Id*. (relying on Comment k). District courts in this circuit have extended this reasoning to hold that there can be no breach of implied warranty with respect to medical devices because they are "unavoidably unsafe products" under Comment k. *See, e.g., Carson v. Atrium Med. Corp.*, 2016 WL 3181414, at *4 (W.D. Pa. June 8, 2016); *Runner*, 108 F. Supp. 3d

at 268 (dismissing implied warranty claim for same reason in case against Bard involving implantable medical device). This Court is guided by these courts' sound reasoning and applies it here to predict that the Pennsylvania Supreme Court would bar a claim for breach of the implied warranty of merchantability against a medical device manufacturer.

Seeking to substantiate the viability of such a claim, Plaintiff points to *McLaughlin v. Bayer Corp.*, 2017 WL 697047, at *3 (E.D. Pa. Feb. 21, 2017). Plaintiff's reliance is, however, misplaced. *McLaughlin* involved neither an implied warranty nor a strict liability claim, and the defendants in that case did not argue for dismissal based on Comment k as Defendants do here. Plaintiff's citation to *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 901 (M.D. Pa. 2017), a case involving an *express* warranty claim, is similarly inapposite. In fact, the *Silver* Court "accept[ed] . . . interpretations that Pennsylvania would not allow an implied warranty claim against a medical device manufacturer" and therefore dismissed the claim. *Id*. Plaintiff also cites to *Kee v. Zimmer, Inc.*, 871 F. Supp. 2d 405 (E.D. Pa. 2012) for the neutral proposition that "the Pennsylvania Supreme Court has not yet adopted any holding that Pennsylvania courts 'bar claims against device manufacturers based on the implied warranties of merchantability and fitness for a particular purpose.'" [ECF 8 at 14]. Plaintiff ignores the fact that after an extensive analysis of Comment k, the *Kee* Court proceeded to bar an implied warranty claim because it predicted—as this Court does—that the Pennsylvania Supreme Court would hold that there is no strict liability for harm caused by medical devices. 871 F. Supp. 2d at 408-10.

Because this Court finds that Plaintiff's strict liability claims are barred as a matter of law, her breach of implied warranty of merchantability claim is barred as well. Count VI is, therefore, dismissed with prejudice.

Products Liability – Negligence

At Count I, Plaintiff asserts products liability claims premised on negligent design, negligent manufacturing, and negligent failure to warn. Defendants move to dismiss these claims, arguing that Plaintiff has failed to allege facts sufficient to plausibly plead the requisite elements. For the reasons set forth below, this Court agrees.[7]

A. Negligent Manufacturing

In products liability claims sounding in negligence, Pennsylvania courts follow the Restatement (Second) of Torts. *Smith*, 251 F. Supp. 3d at 852. Negligent manufacturing claims are governed by § 395.[8] *Lance*, 85 A.3d at 445 n.13. To plead a viable negligent manufacturing claim, "it is necessary to allege some facts that would plausibly suggest that the manufacturer failed to exercise a reasonable standard of care during the 'manufacturing process.'" *Smith*, 251 F. Supp. 3d at 853. Conclusory allegations that a product was negligently manufactured are not, on their own, sufficient to plead a viable claim. *Id*. (holding that "[w]ithout any factual allegation as to the nature of what went wrong during the manufacturing process, there is no plausible road to recovery for negligent manufacturing"); *see also Webb v. Stryker Corp.*, 2017 WL 1406899, at *3 (W.D. Pa. Apr. 20, 2017) (dismissing negligent manufacturing claim and noting that "courts soundly have rejected efforts to apply *res ipsa loquitur* in cases involving medical devices").

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[7] The Pennsylvania Supreme Court has suggested that there is less of a distinction between the treatment of claims asserting negligent manufacturing, design, and failure to warn as compared with strict liability because, in the negligence context, "the main focus is on conduct." *Lance*, 85 A.3d at 458. Nevertheless, the labels are still useful in assessing the sufficiency of such claims on a motion to dismiss. *Smith v. Howmedica Osteonics Corp.*, 251 F. Supp. 3d 844, 852 (E.D. Pa. 2017).

[8] "A manufacturer who fails to exercise reasonable care in the manufacture of a chattel which, unless carefully made, he should recognize as involving an unreasonable risk of causing physical harm to those who use it for a purpose for which the manufacturer should expect it to be used and to those whom he should expect to be endangered by its probable use, is subject to liability for physical harm caused to them by its lawful use in a manner and for a purpose for which it is supplied." Restatement (Second) of Torts § 395.

Defendants move to dismiss Plaintiff's negligent manufacturing claim on the grounds that she fails to plausibly allege "what went wrong during the manufacturing process." In response, Plaintiff directs this Court to six paragraphs in her complaint. [*See* ECF 8 at 9]. These paragraphs allege:

> "Impressions from [a] February 17, 2020 CT scan showed two struts of Defendants' IVC filter perforating through the wall of Plaintiff's inferior vena cava by up to 5 mm." [ECF 1 ¶ 34].
>
> "Defendants failed to exercise reasonable care in the . . . manufacture . . . of the Product because Defendants knew, or should have known, that its Product was inherently dangerous and prone to penetrating or perforating surrounding human tissue and cause [sic] serious physical injuries." [ECF 1 ¶ 41].
>
> "Defendants failed to exercise reasonable care in the . . . manufacturing of the Product because, [sic] it could cause serious personal injuries such as those suffered by Plaintiff during the Product's foreseeable use." [ECF 1 ¶ 44].
>
> "Despite the fact that defendants knew or should have known that the product posed a serious risk of bodily harm to consumers and/or did not provide any additional benefits, Defendants continued to manufacture and market the Product for use by consumers." [ECF 1 ¶ 48].
>
> "Defendants knew or should have known that consumers, including Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above." [ECF 1 ¶ 49].
>
> "As a direct and proximate consequence of Defendants' negligence, Plaintiff sustained serious personal injuries and losses including, but not limited to, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, medical and related expenses, and other losses and damages." [ECF 1 ¶ 52].

As Defendants correctly point out, none of these paragraphs alleges facts concerning Defendants' actual manufacturing process. Notwithstanding, Plaintiff invites this Court to draw the same sort of *res ipsa* inference that led the *Webb* Court to dismiss a negligent manufacturing claim. "Without any factual allegation as to the nature of what went wrong during the manufacturing process," Plaintiff cannot plausibly state a claim for negligent manufacturing. *Smith*, 251 F. Supp. 3d at 853. Plaintiff's negligent manufacturing claim is therefore dismissed.

B. Negligent Design

Negligent design claims are governed by § 398.[9] *Lance*, 85 A.3d at 445 n.13. To plead a viable claim for negligent design, a plaintiff must plead facts to plausibly show that the defendant failed to exercise reasonable care in the adoption of a safe design. *Smith*, 251 F. Supp. 3d at 854. Plaintiff seeks to plead her negligent design claim based on the availability of a safer, feasible alternative design and the legal conclusion that Defendants were negligent in their design. [*See* ECF 8 at 7-8]. Conclusory allegations that a product was negligently designed are not, on their own, sufficient to plead a viable claim. *See, e.g., Smith*, 251 F. Supp. 3d at 854 (dismissing negligent design claim where "[t]he only explicit reference to the product's design is the conclusory allegation that [d]efendants were negligent in such design").

Here, Defendants move to dismiss this claim on the grounds that the allegations in Plaintiff's complaint fail to identify any specific design defect or available reasonable alternative. To support her negligent design claim, Plaintiff directs this Court to four paragraphs of her complaint. [*See* ECF 8 at 8]. Three of these paragraphs merely plead in conclusory fashion that Defendants had a duty of reasonable care in the design of their product (ECF 1 ¶ 40), that their breach of this duty was the direct and proximate cause of Plaintiff's injuries (ECF 1 ¶ 52), and that punitive damages are warranted (ECF 1 ¶ 51). The fourth cited paragraph (ECF 1 ¶ 65) alleges that:

> Defendants knew or should have known of the defective condition [sic] characteristics, and risks associated with the Product. These defective conditions included, but were not limited to: (1) the Product posed a significant and higher risk of failure than other similar IVC filters, such as IVC filter fracture, migration, tilting, and perforation of the vena cava wall; (2) the Product failures result in serious injuries and death; and (3) certain conditions or post-implant procedures,

[9] "A manufacturer of a chattel made under a plan or design which makes it dangerous for the uses for which it is manufactured is subject to liability to others whom he should expect to use the chattel or to be endangered by its probable use for physical harm caused by his failure to exercise reasonable care in the adoption of a safe plan or design." Restatement (Second) of Torts § 398.

> such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the product.

These allegations fail to address either the design of Defendants' product or the availability of safer, feasible alternatives in any level of meaningful detail.[10] District courts in this circuit have consistently dismissed claims resembling Plaintiff's as insufficiently pled. *See, e.g., Smith*, 251 F. Supp. 3d at 853-54 (dismissing negligent design claim because "it cannot be plausibly inferred" that defendants failed to exercise reasonable care in the adoption of a safe design as required by § 398); *Webb*, 2017 LEXIS 60194, at *7 (dismissing claim because plaintiff "ha[d] not identified the particular component of the implant system . . . that was defectively designed"); *Salvio v. Amgen, Inc.*, 810 F. Supp. 2d 745, 754 (W.D. Pa. 2011) (dismissing claim because "baldly stating that there are safer alternatives to [prescription drug], without providing factual support that they exist, is insufficient to survive a 12(b)(6) motion"). Here, because Plaintiff fails to allege facts sufficient to plausibly state a negligent design claim, this claim is dismissed.

C. Negligent Failure to Warn

Negligent failure to warn claims are governed by § 388.[11] *Baldino v. Castagna*, 478 A.2d 807, 810 (Pa. 1984). To assert a viable negligent failure to warn claim, a plaintiff must allege facts sufficient to plausibly show that the defendant "fail[ed] to exercise reasonable care to inform those

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[10] Plaintiff's citation to *Houtz v. Encore Med. Corp.*, 2014 LEXIS 170481, at *5, 16 (M.D. Pa. Dec. 1, 2014) is unavailing. [ECF 8 at 7-8]. The *Houtz* court dismissed a negligent design claim because, like the case *sub judice*, it was "unclear from Plaintiff's Amended Complaint what theory of design defect she is alleging." *Houtz*, 2014 LEXIS 170481 at *17.

[11] "One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous." Restatement (Second) of Torts § 388.

for whose use the product is supplied of the facts which make it likely to be dangerous."[12] *Id*. Federal courts in Pennsylvania have found such claims viable where plaintiffs' complaints contained factual allegations as to the content of the warnings defendants should have provided. *See, e.g., Terrell*, 2014 WL 3746532, at *9-10 (allowing negligent failure to warn claim where plaintiff alleged what information should have been given to her medical providers, setting forth an extensive list); *Houtz*, 2014 LEXIS 170481 at *11-12 (allowing claim where plaintiff alleged that manufacturer should have warned her/her doctors that a specific component of the device was defective and had a high risk of failure).

Here, Defendants argue that "Plaintiff's negligent failure to warn allegations are . . . bereft of any facts about any warnings on the Filter, its labeling, packaging, or other associated materials." To support her negligent failure to warn claim, Plaintiff directs this Court to paragraphs 46-47 of her complaint. [*See* ECF 8 at 10]. These paragraphs allege:

> Defendants breached their duty and also failed to exercise ordinary care in the labeling of the Product and failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury due to use of the Product. Moreover, Defendants over-promoted the benefits of the product.
>
> Defendants breached their duty and were negligent by, but not limited to, undertaking the following actions, misrepresentations, and omissions toward Plaintiff and Plaintiff's healthcare providers:
>
> - Disseminating information about the Product to Plaintiff and/or Plaintiff's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff.
> - Failing to conduct adequate pre-clinical and clinical testing and post marketing surveillance to determine the safety of the Product;
> - Failing to design and/or manufacture a product that could be used safely; and

[12] In the context of a claim alleging failure to warn regarding the risks of a medical device, the manufacturer's duty is to adequately warn the treating physician, *i.e.*, the learned intermediary. *Simon v. Wyeth Pharm*., 989 A.2d 356, 368 (Pa. Super. Ct. 2009).

- In designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable use, which Defendants knew or should have known could cause injury to Plaintiff.

These allegations, however, do not specify what information was missing from Defendants' warnings. Nor do any of the allegations address the precise injury posed by the use of the device. Without this information, Plaintiff has not plausibly stated a connection between her alleged injuries and Defendants' failure to warn. Plaintiff's negligent failure to warn claim is, therefore, dismissed.

Breach of Express Warranty

At Count V of her complaint, Plaintiff asserts a claim for breach of express warranty. Defendants argue that "because [Plaintiff] has not identified the terms of any express warranty, how such warranty was conveyed to her, or how she relied upon it," this claim should be dismissed. This Court agrees.

Under Pennsylvania law, an express warranty arises out of the representations or promises of the seller. 13 Pa. Cons. Stat. § 2313; *see also Sowers v. Johnson & Johnson Medical, Inc.*, 867 F. Supp. 306, 313 (E.D. Pa. 1994). To create an express warranty, "the seller must expressly communicate the terms of the warranty to the buyer in such a manner that the buyer understands those terms and accepts them." *Eiser v. Brown & Williamson Tobacco Corp.*, 2006 WL 933394, at *5 (Pa. Super. Ct. Jan. 19, 2006) (quoting *Goodman v. PPG Indus., Inc.*, 849 A.2d 1239, 1243 (Pa. Super. Ct. 2004)). To plausibly plead an express warranty claim, some level of meaningful detail is required. *See, e.g., Luke v. Am. Home Prods. Corp.*, 1998 WL 1781624, at *6 (Pa. Ct. Com. Pl. Nov. 18, 1998) (dismissing express warranty claim because complaint failed to state "what the warranty allegedly covered, when it was made[,] and to whom it was directed"). Federal courts applying Pennsylvania law in the medical device context have instructed that this includes

such facts as "the specific source of the alleged warranty . . . and the specific statements made." *Doughtery*, 2012 WL 2940727, at *9 n.15. These courts have consistently dismissed claims premised solely on conclusory allegations that medical device manufacturers falsely warranted that their products were safe and fit for their intended use. *See, e.g., Shuker v. Smith & Nephew PLC*, 2015 WL 1475368, at *12 (E.D. Pa. Mar. 31, 2015) (dismissing express warranty claim because alleged only that defendants falsely warranted that medical devices were "'safe and fit for use for the purposes intended, . . . w[ere] of merchantable quality, . . . did not produce any dangerous side effects, and . . . w[ere] adequately tested and fit for [their] intended use'"); *Kester v. Zimmer Holdings, Inc.*, 2010 WL 2696467, at *9–10 (W.D. Pa. June 16, 2010) (dismissing express warranty claim based on the allegation that defendants "expressly warranted that [their devices] were safe and well accepted by users").

To meet her pleading requirements for this claim, Plaintiff directs this Court solely to paragraph 96 of her complaint. [*See* ECF 8 at 14]. In this paragraph, Plaintiff alleges that:

> Defendants, through their officers, directors, agents, representatives, and written literature and packaging, and written media and advertisements, expressly warranted that the Product was safe and effective and fit for use by consumers, was of merchantable quality, did not create the risk of or produce dangerous side effects, including, but not limited to, perforation of the vena cava wall, and was adequately tested and fit for its intended use.

Contrary to Plaintiff's bare assertion, this paragraph does not "specifically cite the language that Defendants used in the promotion of its product, establishing the 'fact or promise' created." [ECF 8 at 14]. Indeed, this paragraph does not provide any "express" language used in the purported express warranty at all. Without any facts to support the existence of an "express warranty," Plaintiff has not plausibly stated a claim for breach of express warranty. Count VI is, therefore, dismissed.

Fraudulent Concealment

At Count VIII, Plaintiff purports to plead a claim of fraudulent concealment. Defendants argue that there is no such independent cause of action under Pennsylvania law. Plaintiff does not address this argument in her response. Nonetheless, this Court notes that fraudulent concealment is an equitable tolling doctrine rather than an independent tort. *Sarpolis v. Tereshko*, 26 F. Supp. 3d 407, 419 (E.D. Pa. 2014); *In re Aspartame Antitrust Litig.*, 2007 WL 5215231, at *4 (3d Cir. Jan. 18, 2007); *In re Processed Egg Products Antitrust Litig.*, 2011 WL 5980001, at *3 (E.D. Pa. Nov. 30, 2011) (quoting *In re Linerboard Antitrust Litig.*, 305 F.3d 145, 160 (3d Cir. 2002)). As such, Plaintiff's fraudulent concealment claim is dismissed with prejudice.[13]

Fraudulent and Negligent Misrepresentation

Plaintiff asserts two other fraud-based claims: fraudulent misrepresentation at Count VII and negligent misrepresentation at Count IX.[14] Defendants argue that these claims are "re-stated failure to warn claims" which must be dismissed because they are barred by *Hahn*.[15] Plaintiff

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[13] Defendants additionally note that, "[a]lthough the Complaint does not identify punitive damages as an independent cause of action, Plaintiff argues that her allegations 'support a claim for punitive damages.'" Plaintiff does not plead a separate claim for punitive damages, nor could she. As this Court has recognized, a claim for punitive damages does not constitute an independent cause of action under Pennsylvania law. *Tily v. Ethicon Inc.*, 2020 WL 5369724, at n.2 (E.D. Pa. Sept. 8, 2020) (Quiñones, J.).

[14] The elements of fraudulent misrepresentation are: "(1) A representation (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation; and (6) the resulting injury was proximately caused by the reliance." *Ira G. Steffy & Son, Inc. v. Citizens Bank of Pa.*, 7 A.3d 278, 290 (Pa. Super. Ct. 2010).

The elements of negligent misrepresentation are: (1) a misrepresentation of a material fact; (2) made when defendant ought to have known its falsity; (3) with intent to induce another to act on it; and (4) which causes injury to a party acting in justifiable reliance on the misrepresentation. *Bilt–Rite Contractors, Inc. v. The Architectural Studio*, 866 A.2d 270, 277 (Pa. 2005). Plaintiff makes no distinction between her fraudulent and negligent misrepresentation claims in arguing for their viability. [*See* ECF 8 at 15-16].

[15] Defendants also argue that "[e]ven if Plaintiff's claim [is] not barred under *Hahn*, the learned intermediary doctrine bars all misrepresentation-based claims in medical product liability cases because plaintiff cannot prove reasonable reliance." [ECF 3 at 12]. While this Court does not reach this argument, it points out that the opinions cited by Defendants address the issue only with respect to claims brought

argues that these claims should be allowed to proceed because she "adequately alleged Defendants' affirmative misrepresentations and overt acts that went beyond mere failure to warn." [ECF 8 at 15]. Plaintiff is mistaken.

As discussed above, the Pennsylvania Supreme Court held in *Hahn* that negligence is the sole theory upon which a plaintiff may recover against a prescription drug manufacturer in a suit based upon the manufacturer's failure to warn. *Hahn,* 673 A.2d at 891. Federal courts in Pennsylvania have relied on this holding to dismiss fraud claims against medical device manufacturers where the allegations in those claims overlap with the elements of a failure to warn claim. *See, e.g., Runner*, 108 F. Supp. 3d at 268 (dismissing fraud claim against Bard in action involving implantable medical device); *Kester v. Zimmer Holdings, Inc.*, 2010 WL 4103553, at *4 (W.D. Pa. Oct. 18, 2010) (holding that fraud allegations "are rooted in a theory of failure to warn," and therefore barred by *Hahn*, where plaintiff alleged merely that defendant manufacturers breached a duty to disclose their product's defective nature); *Kline v. Pfizer, Inc.*, 2009 WL 32477, at *4–5 (E.D. Pa. Jan. 6, 2009) (relying on *Hahn* to hold the same).

Defendants move to dismiss Plaintiff's fraudulent and negligent misrepresentation claims because, *inter alia*, the allegations in these claims do not take them beyond a claim for failure to warn. As noted, Plaintiff responds solely by arguing that "[c]ourts have held that fraud claims concerning medical devices are cognizable if allegations of overt acts that go beyond the mere failure to warn are made."[16] [ECF 8 at 15]. However, Plaintiff fails to allege any overt acts or

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under Pennsylvania's Unfair Trade Practices and Consumer Protection Law (UTPCPL). *See, e.g., McLaughlin*, 172 F. Supp. 3d at 827-32 (holding that the learned intermediary doctrine bars UTPCPL claim and dismissing separate fraudulent and negligent misrepresentation claims on other grounds).

[16] Plaintiff relies on *Cutruzzula v. Bayer Healthcare Pharm., Inc.*, 2015 WL 8488670, at *4-5 (W.D. Pa. Nov. 17, 2015) for this proposition. [*See* ECF 8 at 15]. However, the plaintiff in *Cutruzzula* alleged that defendant manufacturers "affirmatively misrepresented that [their product] is a 'low' or 'no' hormone

affirmative misrepresentations made by Defendants with any degree of specificity. She refers this Court only to paragraphs 118-119 of her complaint to argue to the contrary. [*See* ECF 8 at 15]. These paragraphs allege:

> Defendants knew or believed at the time it made they made [sic] their fraudulent misrepresentations, that their misrepresentations were false and fraudulent regarding the dangers and risks associated with use of Product.
>
> Defendants made their fraudulent misrepresentations intentionally, willfully, wantonly, and with reckless disregarded [sic] and depraved indifference for safety and well-being of users of the Product.

These allegations plainly do not take Plaintiff's fraud claims beyond the scope of failure to warn of the alleged risks of Defendants' product. Plaintiff's argument that "Defendants actively concealed material facts related to the defective nature of the IVC filter, and the dangers associated with it . . . [and] misled Plaintiff and Plaintiff's physician to believe that Defendants' IVC filter was safe and effective for PE and DVT" is similarly unavailing.[17] This Court agrees with Defendants that Plaintiff's misrepresentation claims are "exactly the type of dressed-up failure to warn claims" that other courts have rejected. *Runner*, 108 F. Supp. 3d at 268. Plaintiff's fraud-based claims at Counts VI and IX are, therefore, dismissed with prejudice.

Unjust Enrichment

At Count X, Plaintiff asserts a claim for unjust enrichment. Defendants argue that this claim is not cognizable in a products liability action under Pennsylvania law. Plaintiff does not

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contraceptive, that LNG levels are 'stable' and 'without peaks and troughs,' and that [the product] causes few to no systemic effects." *Cutruzzula*, 2015 WL 8488670 at *5. The lack of specificity in the complaint before this Court stands in stark contrast. Moreover, Defendants here challenge the adequacy of Plaintiff's fraud-based pleadings, while the defendants in *Cutruzzula* moved to dismiss these claims on the sole basis that they were barred as a matter of law. *Id.*

[17] Plaintiff's attendant citation to *Coulter v. Paul Laurence Dunbar Cmty. Ctr.*, 685 Fed. App'x 161 (3d Cir. 2017), a case involving a loan agreement between a lender and a community center rather than a prescription medical device, is inapposite.

respond to this challenge but simply argues that her unjust enrichment claim has been adequately pled.[18] [*See* ECF 8 at 16-17]. For the reasons set forth below, this Court agrees with Defendants that Plaintiff cannot, given the allegations in her complaint as a whole, plausibly state a claim for unjust enrichment.

Courts in this circuit have dismissed unjust enrichment claims in products liability actions where plaintiffs in fact received and used the product they purchased. *See Mazur v. Milo's Kitchen, LLC*, 2013 WL 3245203, at *10 (W.D. Pa. June 25, 2013) (dismissing claim on grounds that it "cannot be said" that benefit bestowed on defendants in form of profit from sale was wrongly secured because plaintiff "nevertheless purchased, received, and used the product"). In the prescription drug arena, these courts have held that "[u]njust enrichment is not a substitute for failed tort claims in Pennsylvania, but, instead, will generally be used to imply quasi-contract liability." *Zafarana v. Pfizer Inc.*, 724 F. Supp. 2d 545, 560 (E.D. Pa. 2010); *see also Tatum*, 2012 WL 5182895, at *4–*5 (finding that alleged failure to warn about known risks associated with prescription medication did not state claim for unjust enrichment because there was no allegation that defendants "refused to provide a service or goods after [plaintiff] provided defendants with a benefit"). Based on the case law cited, this Court agrees that an unjust enrichment claim is not cognizable in a products liability action because the allegations required to plausibly plead such a claim are incompatible with the elements of tort claims premised on products liability.

[18] To plead a viable claim for unjust enrichment, a plaintiff must plead facts sufficient to plausibly show: (1) benefits conferred on defendant by plaintiff; (2) appreciation of such benefits by defendant; and (3) acceptance and retention of such benefits under such circumstances that it would be inequitable for defendant to retain the benefit without payment of value. *Sovereign Bank v. BJ's Wholesale Club, Inc.*, 533 F.3d 162, 180 (3d Cir. 2008) (citing *Limbach Co. LLC v. City of Philadelphia*, 905 A.2d 567, 575 (Pa. Cmwlth. Ct. 2006)).

As noted, Plaintiff does not address the legal cognizability of her unjust enrichment claim in her response.[19] [*See* ECF 8 at 16-17]. Instead, she argues only that the applicability of unjust enrichment "depends on the facts of [the] particular case." [*Id*. at 16]. Here, the facts of Plaintiff's products liability complaint are unavailing. Plaintiff avers that she received Defendants' product during a medical procedure "[i]n or around 2003," and that the product remained in her body for at least the next seventeen years. [ECF 1 ¶¶ 30, 34]. In her response, Plaintiff directs this Court only to paragraphs 166-169 of her complaint. [*See* ECF 8 at 17]. This allegation that "Plaintiff has not received the safe and effective Product for which [she] paid" does not satisfy the elements of unjust enrichment. Because Plaintiff acknowledges that she received and used Defendants' product, she cannot plausibly state a claim for unjust enrichment. This claim is, therefore, dismissed with prejudice.

Leave to Amend

In her response, Plaintiff requests leave to amend her complaint in the event this Court dismisses her claims. If properly requested, leave to amend "should . . . 'be freely given when justice so requires.'" *See Fletcher-Harlee Corp. v. Pote Concrete Contractors, Inc.*, 482 F.3d 247, 252 (3d Cir. 2007) (quoting Fed. R. Civ. P. 15(a)). The Third Circuit has held that "[d]ismissal without leave to amend is justified only on the grounds of bad faith, undue delay, prejudice, or futility." *Alston v. Parker*, 363 F.3d 229, 236 (3d Cir. 2004).

Here, for the reasons set forth above, Plaintiff's claims for strict liability, breach of implied warranty of merchantability, and fraudulent concealment are barred as a matter of law, and no additional facts would render her claim for unjust enrichment viable. As such, amendment of these

[19] Indeed, as Defendants point out, Plaintiff does not and cannot cite a single products liability case in which an unjust enrichment claim survived 12(b)(6) alongside a negligence, strict liability, or fraud-based claim.

claims would be futile. Plaintiff's claims premised on negligence, breach of express warranty, fraudulent misrepresentation, and negligent misrepresentation, however, suffer from mere pleading inadequacies. Therefore, Plaintiff is granted leave to amend these claims, provided there are facts to support the requisite amendments.

CONCLUSION

For the reasons stated herein, Defendants' motion to dismiss Plaintiff's complaint is granted as to the ten counts asserted. Plaintiff, however, is granted leave to amend *only* her claims based on negligence (Count I), breach of express warranty (Count V), fraudulent misrepresentation (Count VII), and negligent misrepresentation (Count IX).

An Order consistent with this Memorandum Opinion follows.

NITZA I. QUIÑONES ALEJANDRO, U.S.D.C., J.